

REMARKS

Claims 28, 30-32, 34, 39 and 41 remain pending in the present application. Claim 28 is amended to address formal matters discussed in the Examiner Interview of October 6, 2009. No new matter is added.

During an interview conducted with the Examiner on October 6, 2009, Applicants' representative and the Examiner agreed that the "consisting of" transitional phrase in claim 28 should be adequate to overcome the prior art rejections.

The Examiner requested Applicants' representative to (1) amend claim 28 such that the components of the composition were in the same portion of the claim. Such an amendment is submitted herewith, merely re-arranging the subject matter of claim 28 for clarity.

Entry of the amendment is requested under 37 C.F.R. 1.116, since the amendment raises no new issues and presents no new matter, as discussed below. In the alternative, entry of the amendment is requested in order to place the claim into better form for consideration on appeal.

Rejection under 35 U.S.C. §112, first paragraph

Claims 28, 30-32, 34, 39 and 41 are rejected under 35 U.S.C. §112, first paragraph for failing to comply with the written description requirement. Applicants traverse this basis for rejection and respectfully request reconsideration and withdrawal thereof.

At page 2 of the outstanding Office Action, the Examiner states:

The recitation that [the] delivery vehicle consists of tranilast was not envisioned...It is suggested that applicant direct the examiner to section of the specification as originally filed that supports the claimed composition consisting of tranilast and polymer and an optional therapeutic agent.

In response, Applicants direct the Examiner's attention to the following paragraphs, reproduced here in part and highlighted for the Examiner's convenience, numbered according to U.S. Published Patent Document 2005/0106230, which corresponds to the present application.

[0023] A large variety of alternative sustained release delivery vehicles for administering Tranilast or analogs thereof also are contemplated as within the scope of the present invention when containing therapeutically effective amounts of Tranilast. Suitable delivery vehicles include, but are not limited to, microcapsules or microspheres; liposomes and other lipid-based release systems; absorbable and/or biodegradable mechanical barriers; polymeric delivery materials such as, but not limited to, polyethylene oxide/polypropylene oxide block copolymers (i.e., poloxamers), poly(orthoester)s, poly(vinyl alcohol)s, poly(anhydride)s, poly(methacrylate)s, poly(methacrylamide)s, anionic carbohydrate polymers, poly(hydroxybutyric acid)s, and polyacetals.

[0029] Moreover, alternative delivery systems based on biodegradable polymers and that are suitable for use in accordance with the present invention, for example, fibers, films, foams, or filaments comprising the active agents, also are contemplated as being within the scope of the present invention when containing effective amounts of Tranilast or analogs thereof.

Accordingly, Applicants submit that a composition of Tranilast and a biodegradable polymer in the form of fibers, films, foams or filaments is sufficiently supported in the present specification.

Support for the additional therapeutic agents can be found in paragraphs [0037]-[0038].

It is respectfully submitted that such recitation would convey with reasonable certainty to one of ordinary skill in the art that the applicant was in possession of the subject matter as now claimed. (See: *Union Oil v. Atlantic Richfield Co.*, 54 USPQ2d 1227, 1232 (Fed. Cir. 2000). Moreover, it is respectfully submitted that applicant's disclosure would clearly allow one of ordinary skill in the art to immediately discern that applicant's invention was directed to and included a composition of Tranilast and a biodegradable polymer in the form of fibers, films, foams or filaments. (See: *Purdue Pharma L.P. v. Faulding Inc.*, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000),

Clearly the application when considered as a whole, supports the present claim language and meets the written description requirement of 35 U.S.C. §112.

In view thereof, the applicants respectfully request that the rejection of claims 28, 30-32, 34, 39 and 41 under 35 U.S.C. §112, first paragraph for failing to comply with the written description requirement, be withdrawn.

Rejection under 35 U.S.C. §112, second paragraph

Claims 28, 30-32, 34, 39 and 41 are rejected under 35 U.S.C. §112, second paragraph as being indefinite. Applicants traverse this basis for rejection and respectfully request reconsideration and withdrawal thereof.

Applicants request reconsideration and withdrawal of the rejection in view of the accompanying amendment, which indicates that the optional therapeutic agent is in addition to Tranilast.

In view thereof, the applicants respectfully request that the rejection of claims 28, 30-32, 34, 39 and 41 under 35 U.S.C. §112, second paragraph as being indefinite, be withdrawn.

**Rejection for provisional nonstatutory double patenting over copending
application no. 10/780,452 in view of Chandrasekar et al.
Or Miyazawa et al.**

Claims 28, 30-32 and 39-41 are provisionally rejected for nonstatutory double patenting over claims 14-19, 21-24 and 27-41 of copending application no. 10/780,452, in view of Chandrasekar et al. ("Platelets and Restenosis") or Miyazawa et al. ("Effects of pemirolast and tranilast on intimal thickening after arterial injury in the rat"). Reconsideration of the double patenting rejection is requested in view of the accompanying amendment herein.

On notification of allowable subject matter Applicants will consider submitting a Terminal Disclaimer over copending application no. 10/780,452.

In view of the foregoing, it is respectfully submitted that the present claims are in condition for allowance. Prompt notification of allowance is respectfully requested.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Account No. 50-2478 (14788).

If the Examiner has any questions or wishes to discuss this application,

U.S. Serial No. 10/797,367
Response dated: April 8, 2010
Response to Office Action dated January 8, 2010

the Examiner is invited to contact the undersigned representative at the number set forth below.

Respectfully submitted,

Date: April 8, 2010

A handwritten signature in dark ink, appearing to read "Michael J. Mlotkowski", written over a horizontal line.

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